510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K060964

MAY 25 2006

Submitter Information

Address:	Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355
Contact person:	Diana L. Wolaniuk, (610) 240-3917
Summary preparation date:	April 4, 2006

Name of Device

Trade/Proprietary Name:	ARCHITECT® BNP Assay
Common/Usual Name:	BNP (B-Type Natriuretic Peptide) Test
Classification Name:	Test, Natriuretic Peptide

Predicate Device

ABBOTT AxSYM® B-Type Natriuretic Peptide (BNP) Microparticle Enzyme Immunoassay (MEIA) Test

Device Description

ARCHITECT BNP assay is a two-step immunoassay for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma using CMIA technology with flexible assay protocols, refereed to as Chemiflex®.

In the first step, sample and anti-BNP coated paramagnetic microparticles are combined. BNP present in the sample bind to the anti-BNP coated microparticles. After washing, anti-BNP acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of BNP in the sample and the RLUs detected by the ARCHITECT *i* System optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

Intended Use

Reagent Kit
The ARCHITECT BNP assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma on the ARCHITECT *i* System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.

Calibrator Kit
The ARCHITECT BNP Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma. Refer to the ARCHITECT BNP reagent package insert and ARCHITECT *i* System for additional information.

Control Kit
The ARCHITECT BNP Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System (reagents, calibrators, and instrument), when used for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma. Refer to the ARCHITECT BNP reagent package insert and ARCHITECT *i* System for additional information.

Statement of Substantial Equivalence

The ARCHITECT BNP assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma on the ARCHITECT *i* System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.

The ARCHITECT BNP Assay kit is substantially equivalent to the AxSYM BNP Assay. Both of the devices are IVD products and are indicated for the quantitative determination of BNP assay values (human B-type natriuretic peptide) and used as an aid in the diagnosis and assessment of severity of heart failure.

A study was performed with guidance from NCCLS Protocol EP9-A2[1] to compare the ARCHITECT BNP assay to the AxSYM BNP assay. EDTA plasma samples form 171 individuals (128 heart failure patients, 43 non-heart failure individuals) were tested with both assays. These samples were collected from populations of individuals with and without heart failure. The results from the Passing-Bablok[2] linear regression analysis is summarized in the following table.*

ARCHITECT BNP vs. AxSYM BNP					
Regression Method	Specimen Type	N	Correlation Coefficient	Intercept (95% CI)	Slope (95% CI)
Passing-Bablok**	EDTA Plasma	171	0.96	-38.32 (-48.26 to –28.50)	1.03 (0.98 to 1.09)

Sample Range (ARCHITECT): 0 –3702 pg/mL
Sample Range (AxSYM): 50 – 3103 pg/mL

* Representative data; variables such as differences in sampling size and population may impact the correlation of the assay. Therefore, results in individual laboratories may vary from these data.

** A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.

[1] National Committee for Clinical Laboratory Standards. *Method comparison and bias estimation using patient samples; Approved Guideline-Second Edition.* NCCLS Document EP9-A2, Wayne, PA: NCCLS, 2002.
[2] Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. *J Clin Chem Clin Biochem* 1983; 21(11)709-20.

A comparison of the features of the ARCHITECT BNP assay device and the AxSYM BNP assay device are as follows:

	ARCHITECT BNP (Proposed Device)	**AxSYM BNP (Predicate Device) K033606**
Device Type	*In vitro* diagnostic	*In vitro* diagnostic
Classification and Product Code	Class II, NBC	Class II, NBC
Principle of Operation	Chemiluminscent Microparticle Immunoassay (CMIA)	Microparticle Enzyme Immunoassay (MEIA)
Product Usage	Clinical and Hospitals laboratories	Clinical and Hospitals laboratories
Intended Use	The ARCHITECT BNP assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma on the ARCHITECT *i* System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.	AxSYM BNP is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma on the AxSYM System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.
Type of Specimen	EDTA Plasma	EDTA Plasma
Specimen Collection Method	Plastic collection tubes	Plastic collection tubes
Capture Antibody	Anti-BNP (106.3) mouse monoclonal	Anti-BNP (106.3) mouse monoclonal
Conjugate Antibody	Anti-BNP (BC203) mouse monoclonal	Anti-BNP (BC203) mouse monoclonal
Calibrator	6 levels (0 – 5000 pg/mL)	6 levels (0 - 4000 pg/mL)
Controls	3 levels (Low = 90 pg/mL, Medium = 500 pg/mL, High = 3500 pg/mL)	3 levels (Low = 100 pg/mL, Medium = 440 pg/mL, High = 1500 pg/mL)
Interpretation of Results	Calibrator Curve A direct relationship exists between the amount of BNP in the sample and the light detected by the instrument system	Calibrator Curve A direct relationship exists between the amount of BNP in the sample and the light detected by the instrument system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Diana L. Wolaniuk
Clinical and Regulatory Affairs Specialist
Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

MAY 25 2006

Re: k060964
Trade/Device Name: ARCHITECT® BNP
ARCHITECT BNP Reagent Kit
ARCHITECT BNP Calibrator Kit
ARCHITECT BNP Control Kit
Regulation Number: 21 CFR§862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: Class II
Product Code: NBC, JIT, JJX
Dated: April 5, 2006
Received: April 7, 2006

Dear Ms. Wolaniuk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060964

Device Name: ARCHITECT® BNP

Indications For Use:

ARCHITECT BNP Reagent Kit
The ARCHITECT BNP assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma on the ARCHITECT *i* System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.

ARCHITECT BNP Calibrator Kit
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ARCHITECT BNP Control Kit
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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060964